REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the Claims

Claim 1 has been amended to recite only rosiglitazone and a polymer.

No new matter has been introduced as a result of the claim amendments.

35 U.S.C. §112 Rejections

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office asserts that claim 1 is vague and indefinite.

Claim 1 has been amended to remove the phrase "at least one" and indicate that the coating comprises rosiglitazone and the polymer. Therefore, Applicants respectfully request the withdrawal of the rejection on this basis.

35 U.S.C. §103 Rejections

Claims 1, 5-7, 9, 11 and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Berg et al. (US 5,464,650) in view of Su et al. (Journal of Clinical Investigation, 1999). Applicants respectfully disagree.

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest all claim elements. S*ee, e.g., KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *Pharmastem Therapeutics v. Viacell et al.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); MPEP § 2143(A)(1). In addition to demonstrating that all elements were known in the prior art, the Office must also articulate a reason for combining the elements. See, *e.g., KSR* at 1741; *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 243 Fed. Appx. 592, 595-596 (Fed. Cir. 2007) citing *KSR*. Further, the Supreme Court in *KSR* also stated that that "a court *must* ask whether the improvement is more than the predictable use of prior art elements according to their established

functions." *KSR* at 1740; emphasis added . As such, in addition to showing that all elements of a claim were known in the prior art and that one of skill had a reason to combine them, the Office must also provide evidence that the combination would be a predicted success.

Berg teaches an intravascular stent coated with a polymer which allows for the sustained release of a drug to vascular tissue. Many different classes of drugs are disclosed in column 5, lines 19-40 including the class of anti-inflammatory agents. The only anti-inflammatory agents explicitly cited by Berg are glucocorticoids (specifically dexamethasone and betamethasone) and aspirin (Berg, column 5 lines 23-31). Berg does not teach or suggest other types of anti-inflammatory agents.

Su et al. teaches the use of BRL 49653 (rosiglitazone) to reduce epithelial inflammation in colonic epithelium (Su, page 383, 2nd column, 3rd paragraph). Su teaches that PPAR-γ is a member of the nuclear hormone receptor superfamily whose ligands include prostanoids, polyunsaturated fatty acids, a variety of nonsteroidal anti-inflammatory drugs (NSAIDS) and a new class of oral antidiabetic agents, the thiazolidinediones (Su, page 383, 2nd column, 2nd paragraph).

The Office asserts that it would have been obvious to one of ordinary skill in the art to combine the teachings of Berg and Su. Berg discloses the use of various classes of drugs that may be combined with polymeric coatings on a stent. These classes of agents include antiplatelets, anticoagulants, antimitotics, antioxidents and antimetabolites. The three anti-inflammatory agents specifically cited are steroids and aspirin. While aspirin is generally considered to be a non-steroidal anti-inflammatory agent, aspirin actually causes gastrointestinal bleeding and therefore would not be considered by one of ordinary skill in the art as useful for reducing inflammation of the colonic epithelium. This broad-brush disclosure does not teach, or suggest, PPAR-γ inhibitors, certainly not rosiglitazone.

Furthermore, in combining references there must be a reasonable expectation of success. The mere fact that Berg suggests the class of anti-inflammatories does not mean that each and every member of that class will be effective in delivery from a stent to the blood vessel. Su teaches rosiglitazone for use systemically as a means to reduce colon epithelial inflammation. There is no expectation that such an agent meant for systemic administration for treating colon

epithelial inflammation would be effective for site-specific controlled-release delivery from a stent to prevent or treat inflammation in a vessel endothelium, as is required in the claims under rejection. For example, a systemic agent is metabolized through various mechanisms and systems of the body, most importantly, through the liver. Site-specific delivery to the lining of a blood vessel is local administration which bypasses such mechanisms and systems. There is no expectation that a systemic drug for one disease will be effective for local administration to treat another unrelated disease.

Therefore, Applicants respectfully assert that the Office has not established *prima facie* obviousness of the pending claims over Berg et al. in view of Su et al. and request the withdrawal of the rejections on this basis

Double Patenting Rejections

Claims 1, 5-7, 9, 11 and 27 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of co-pending application number 11/383,262 and unpatentable over claims 15-18 of co-pending application number 11/619,122 in view of Berg et al. and in further view of Su et al. The Office has asserted that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope.

Co-pending application 11/383,262 was filed on May 15, 2006 and co-pending application 11/619,122 was filed on January 2, 2007, claiming priority to a provisional application filed April 11, 2006. The instant application is the earlier filed application in both instances. Furthermore, neither of the two co-pending applications have yet received a first office actions on the merits, however, in co-pending application 11/383,262, claims 15-26 have been withdrawn in response to a restriction requirement. Therefore the claim scope of any patents issuing from these co-pending applications is not possible to determine at this time.

Therefore, Applicants respectfully request that the provisional obviousness-type double patenting rejections be held in abeyance until the Office issues an indication of allowability in this application

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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